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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/207,161	12/07/98	HILLMAN J	PF-0208US

EXAMINER	
CARLSON, K	
ART UNIT	PAPER NUMBER
1653	11

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LEGAL DEPARTMENT
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

U.S. G.P.O. 1999 460-693

Office Action Summary

Application No.	Applicant(s)
09/207,161	Hillman et al.
Examiner	**Group Art Unit**
Karen Cochrane Carlson	1653

☒ Responsive to communication(s) filed on *Feb 28, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1 and 11-20* is/are pending in the applicat

Of the above, claim(s) *12-20* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1 and 11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

This Office Action is in response to Paper #8, filed February 28, 2000.

Applicant's election with traverse of Invention I, Claims 1 and 11 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the search for the antibody, agonist, antagonist, and the method is encompassed by the search for the protein. This is not found persuasive because the searches are not wholly overlapping and the issues surrounding each of these Inventions are separate and distinct from the issues of the protein.

Further, Applicants desire new claims 19 and 20 to be examined as well, stating that the scope of the product of the elected invention is the same in these methods. These methods are distinguished from the product as a product and process of using the product and therefore are patentably distinct.

Applicants further want the claims of Invention VI rejoined because these claims are stated to be directed to the product of the patented parent application. This is a separate application, with a different elected invention and these claims will not be considered during the prosecution of this applicaiton.

The restriction requirement is made FINAL.

Claims 2-10 have been canceled. Claims 12-20 have been withdrawn from further consideration because these Claims are directed to non-elected Inventions. Claims 1 and 11 are currently under examination.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. Correction is required.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the

inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. The specification states that the IMP-2 protein is presumed to be a type II integral membrane protein and provides a method to confirm this presumption (page 50, line 6). The type II integral membrane proteins are stated to have an amino terminal cytoplasmic domain that is typically small and generally lacks enzymatic activity and are not directly involved in transmembrane signaling. The carboxy terminal extracellular domain typically comprises the active portion of the protein such as enzymatic or receptor binding domain activity (para. bridging pages 1-2). At page 2, para. 1, the specification compares IMP-2 to the mouse multigene E24 failing of type II integral membrane proteins and discusses expression patterns of mouse *Itm2* gene. At page 14, paras 104, the specification teaches the biochemical characteristics of IMP-2. In no place does the specification teach the function of IMP-2 protein. The IMP-2 protein sequence is deduced from the cDNA sequence and the protein itself has not been produced.

The specification teaches that IMP-2 can be used to treat liver diseases including liver tumors (page 4, line 29) and to treat a variety of tumors (page 5, line 3). IMP-2 is also taught to be useful for the diagnosis, prevention, or treatment of diseases associated with abnormal liver tissue including tumors. At page 28, para. 1 the specification teaches that IMP-2 or

fragments or derivatives thereof may be administered to a subject to treat disorders associated with abnormal liver functions as well as a variety of tumors. Conditions and diseases to be treated include liver tumors, primary biliary cirrhosis, lung, brain, prostate, breast, and bladder tumors.

The asserted utilities set forth in the specification are considered to be general utilities that would be applicable to the broad class of the invention. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Because Applicant has not disclosed any specific and substantial utility for the claimed invention, credibility will not be assessed.

Claims 1 and 11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not teach naturally occurring amino acid

sequences having at least 90% sequence identity to an amino acid sequence of SEQ ID NO:1. Therefore, one skilled in the art would not know what this naturally occurring sequence would look like, or if the sequence represents a functional protein.

The specification does not teach biologically active fragments of SEQ ID NO:1. As noted above, no biological activity has been attributed to SEQ ID NO:1, and therefore no assay can be used to determine a biological activity of the fragment of SEQ ID NO:1.

The specification does not teach immunological fragments of SEQ ID NO:1. No immunological fragments has been made from SEQ ID NO:1, and therefore it cannot be determined what an immunological fragment of SEQ ID NO:1 is, or how to determine it.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Deleersnijder et al. (1996; J. Biol. Chem. 271:19475-19482). As noted by Applicants in Figure 2, Deleersnijder et al. teach a E24AMM protein comprising fragments of SEQ ID NO:1. Therefore, Deleersnijder et al. teach biologically active fragments and immunogological fragments of SEQ ID NO:1.

Art of record:

Vidal et al. (24 June 1999; Nature 399:776-781) teach SEQ ID NO:1. SEQ ID NO:1 is a precursor of the ABri amyloid protein.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is (703) 308-0034. The Examiner can normally be reached daily except alternate Fridays from 7:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. The OFFICIAL fax phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

Karen Cochrane Carlson, Ph.D.

Primary Examiner